

# **ATTACHMENT E**

**ATTACHMENT E: STIPULATED FACTS**

**1. The following material facts are admitted by the parties and require no proof:**

- a. The Defendants in this case are C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (“BPV”). BPV is the wholly-owned subsidiary of C. R. Bard, Inc. Throughout this case, including in this pretrial order, the jury instructions and the verdict form, C. R. Bard, Inc. and BPV will be referred to collectively as “Bard” or “Defendants.”
- b. The product that is the subject of this lawsuit is a Bard Recovery® IVC Filter that was designed, tested, manufactured, marketed and sold by Bard;
- c. The Recovery Filter consists of a main cap to which twelve struts (six “arms” and six “legs”) are attached.
- d. The Recovery Filter is constructed of a nickel-titanium alloy called Nitinol.
- e. The Recovery Filter is a medical device that is implanted in the inferior vena cava (“IVC”), the largest vein in the human body.
- f. The intended purpose of the Filter is to catch blood clots to prevent them from traveling to the heart or lungs.

- g. The predicate devices for the Recovery filter were the Simon Nitinol filter and the Titanium Greenfield Vena Cava filter.
- h. The United States Food and Drug Administration (“FDA”) cleared the Recovery Filter for commercial availability through the 510(k) process outlined in the Food, Drug and Cosmetic Act (“FCDA”).
- i. The Recovery Filter was cleared by the FDA for permanent use on November 27, 2002, and on July 25, 2003 for retrievable use.
- j. The Recovery® filter was introduced to the market in December 2002 and sold until September 2005.
- k. Defendants stopped selling the Recovery filter in September 2005 at the time Defendants began selling the G2 filter.
- l. In September 2004, Plaintiff Jennifer Coker was diagnosed with a recurrent pulmonary embolism while taking anticoagulation medicine.
- m. Ms. Coker was under the care of Stephanie Eaton, M.D. who recommended an IVC filter for Ms. Coker. Dr. Eaton referred Ms. Coker to Jason Levy, M.D., an interventional radiologist, to consult with Ms. Coker regarding placement of that device.

- n. On September 27, 2004, Dr. Levy implanted a Recovery filter in Ms. Coker's inferior vena cava at Northside Hospital in Atlanta, Georgia.
- o. The specific Instructions for Use pertinent to the Recovery® filter implanted in Ms. Coker were the December 2003 Instructions for Use.

**Plaintiff's Note**

Plaintiff notes that Defendants have refused to fully cooperate pursuant to the Local Rules and stipulate to the facts which follow which have been admitted by their own expert, Piotr Sobieszczyk, M.D., an attending physician in the Cardiovascular Division at Brigham and Women's Hospital and its Vascular Medicine Section. Dr. Sobieszczyk also serves as an Associate Director of the Cardiac Catheterization Laboratory with an academic appointment as Instructor in Medicine at Harvard Medical School.

Plaintiff repeatedly asked Defendants for a reason why they could not stipulate to the facts and was provided only one minor explanation. The Defendants had argued that one statement made it appear that there was still a broken filter fragment in Ms. Coker's heart. This objection was cured by setting forth a separate statement that the broken strut/fragment was no longer in her heart. Defendants

have still refused to stipulate that the filter even fractured or migrated, despite their being radiographic proof of same, and testimony by their own expert.

These are the factual statements that Plaintiff requested that Defendants stipulate to:

- *Sometime after the September 27, 2004 implantation, Ms. Coker's Recovery filter fractured.* Sobieszczyk Deposition, P42L16 – P43L11.

16 Q. And you know in this case from your review  
17 of the imaging, looking at the stack in front of  
18 you, you know that though it was not recognized at  
19 the time that in 2006 a fractured fragment of the  
20 filter, the IVC filter, was visualized in the  
21 patient's, that is, Jennifer Coker's, left  
22 ventricle; you know that, don't you?

23 A. I looked at that CT dated June 7, 2006;  
24 correct.

25 Q. And interestingly, you didn't look at that

1	until it was sent to you just a few weeks ago, two
2	weeks ago; is that true?
3	<b>A. Last week; correct.</b>
4	Q. So in your report, you actually said that
5	you had not reviewed that imaging; correct?
6	<b>A. Correct.</b>
7	Q. Now having reviewed that imaging, you agree
8	with Dr. Singh that what we are seeing in that CT of
9	June 7, 2006 is more than likely a fractured
10	fragment of the Recovery Bard filter?
11	<b>A. Correct.</b>

Defendants refuse to stipulate to this fact despite stipulating in the Pretrial Order in *Wright v. C.R. Bard, et al*, Northern District of Texas, Civil Action No. 3:19-cv-02176-S (a Recovery filter case) that: “Plaintiff’s filter remains implanted in her inferior vena cava; however, the filter has fractured, and one piece is in her heart and another is in her lungs.”

- *An arm of the Recovery filter then embolized to Ms. Coker’s heart.*  
Sobieszczyk Deposition, P43L19-P44L4.

19 Can you tell us, do the arrows which are  
20 set forth on Sobie Exhibit No. 5, do these  
21 accurately point to the Recovery filter fragment in  
22 the heart, in your opinion?

23 **A. They do.**

24 Q. And in your opinion, how did the fragment  
25 of the Bard Recovery filter end up in Ms. Coker's

770-343-9696

Tiffany Alley Global Reporting & Video

Page 43

Coker vs. CR Bard

Piotr Sobieszczyk, M.D.

05/27/2015

1 left ventricle?

2 **A. The length of that fragment appears to be**  
3 **probably an upper arm of the filter. It fractured**  
4 **and embolized to the heart.**

- *The Recovery arm was no longer seen in the heart on imaging as of November 2012. Sobieszczyk Deposition, P49L13-20.*

13 Q. Well, and we know in this case by 2012, the  
14 fragment that was in Jennifer Coker's left ventricle  
15 is no longer there. We know that from the imaging  
16 studies; correct?

17 **A. Correct.**

18 Q. So we know that it did move at some point;  
19 correct?

20 **A. At some point it did.**

- *November 14, 2012 imaging shows that one arm was separated from the IVC filter and embedded through the wall of the inferior vena cava and extending into the ovarian vein. Sobieszczyk Deposition, P75L8-24.*

8	Q. Let me show you what has been marked as
9	Sobie <u>Exhibit 10</u> and ask you if what you are seeing
10	on this exhibit is consistent with your prior
11	review, that is, before coming into this deposition,
12	review of the CT abdomen of November 14, 2012.
13	A. I believe what I commented on when I looked
14	at it was seeing one of the arms separated from the
15	core of the filter, embedded through the wall of the
16	IVC and extending into the surrounding structures,
17	which in this case is the ovarian vein.
18	I think the arrow demonstrates that.
19	Q. So if I were to ask you, looking at Sobie
20	<u>Exhibit No. 10</u> , whether or not this exhibit with
21	arrows accurately demonstrates the presence of the
22	Recovery filter fragment in Ms. Coker's right
23	ovarian vein, would the answer be yes?
24	A. Yeah.

- *The November 14, 2012 imaging also shows a filter fragment in the right peroneal artery. Sobieszczyk Deposition, P78L24 - P79L23.*

24	Q. And does Sobie <u>Exhibit 9</u> demonstrate,
25	including by use of the arrows, where this thin

770-343-9696 Tiffany Alley Global Reporting & Video Page 78



1 metallic fragment is accurately, from your prior  
2 review of the studies?

3 **A. I have noted that fragment there**  
4 **previously. The arrows are correct.**

5 Q. And do you agree in reasonable medical  
6 probability that this fragment represents one of the  
7 limbs of the Recovery filter?

8 **A. I think it's a fair statement, yes.**

9 Q. And we know for this fragment to get into  
10 the arterial circulation, more than likely -- more  
11 likely than not, this fragment had to travel through  
12 the PFO in the heart to get to the left side;  
13 correct?

14 **A. Correct. This is the fragment that was in**  
15 **the left ventricle previously.**

16 Q. Okay. You're saying that the fragment  
17 shown in Sobie Exhibit 9, to be accurate for the  
18 record, is the fragment that was previously in  
19 Ms. Coker's left ventricle; correct?

20 **A. Based on the surrounding studies; correct.**

21 Q. And that is your opinion within reasonable  
22 medical certainty or probability; correct?

23 **A. Correct.**

- *On imaging, the IVC filter legs perforate the walls of the inferior vena cava.*

Sobieszczyk Deposition, P78L1-6.

1 Q. And if we take a look at the second page of  
2 Sobie Exhibit No. 8, do you agree that that  
3 demonstrates the IVC filter perforation through the  
4 walls of the IVC?

5 A. The legs are extending out of the IVC,  
6 perforating it, the wall; correct.

### **Defendants' Response to Plaintiff's "Note"**

The facts to which Plaintiff seeks to require Defendant to stipulate are complicated medical conditions that Defendants believe need to be presented by an expert witness and not presented in a simplified Stipulation of Fact. For example, Plaintiff omits pages of Dr. Sobieszczyk's deposition explaining these conditions. Likewise, Plaintiff by and through her experts can present these facts.

Further the fact that Defendants stipulated to a fact in another case involving a different plaintiff, with different medical conditions, different expert witnesses, and different is irrelevant and not the basis for a Stipulation in this case.

### **Plaintiff's Response**

Plaintiff does not seek to preclude either side from expounding on the above facts and explaining how or why the events occurred and what occurred (or didn't from the defense position) as a result of such fracture and migration. Plaintiff will obviously need expert testimony to prove liability and causation. However, it is a

*fact* that the filter fractured and that it migrated, which Defendants refuse to stipulate to.